

**Preliminary Amendment**

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Applicant(s): Salman Baig et al.

Serial No. Unknown (National Stage of PCT/US00/10672)

Filed: Herewith (Int'l. Filing Date: April 20, 2000)

For: CYSTEINE PROTEASE AND INHIBITORS FOR PREVENTION AND TREATMENT OF  
NEUROCYSTICERCOSIS

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(for convenience, all pending claims, including those added hereby, are provided in Appendix A).

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4. (AMENDED) A vaccine comprising a cyst wall cysteine proteinase or a polynucleotide having a nucleic acid sequence encoding a cyst wall cysteine proteinase; and a pharmaceutically acceptable carrier.

5. (AMENDED) A method for preparing the vaccine of claim 4 comprising mixing a cyst wall cysteine proteinase or a polynucleotide having a nucleic acid sequence encoding a cyst wall cysteine proteinase; and a pharmaceutically acceptable carrier.

6. (AMENDED) A vaccine comprising at least one component selected from the group consisting of (a) a polypeptide comprising a cyst wall cysteine proteinase or an immunogenic polypeptide subunit thereof and (b) a polynucleotide comprising a nucleotide sequence encoding a polypeptide comprising a cyst wall cysteine proteinase or an immunogenic polypeptide subunit thereof; and a pharmaceutically acceptable carrier.

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8. (AMENDED) A method for treating an animal harboring a *Taenia* infection comprising administering to the infected animal the vaccine of claim 6, wherein administration of the vaccine is effective to eliminate the parasite from the animal or to prevent or delay the appearance of cysticercosis or neurocysticercosis the animal.

9. (AMENDED) A method for protecting an animal against a *Taenia* infection comprising administering to an uninfected animal the vaccine of claim 6, wherein administration of the composition is effective to prevent subsequent infection of the animal by the parasite or to prevent the development of cysticercosis or neurocysticercosis in the animal after subsequent infection by the parasite.

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A<sup>2</sup> *corrected*  
10. (AMENDED) The method of claim 8 wherein the animal is a pig or a human and the *Taenia* infection is a *T. solium* infection.

A<sup>3</sup>  
14. (AMENDED) The pharmaceutical composition of claim 12 wherein R comprises a chemical moiety selected from the group consisting of a carboxylic acid derivative, an amide derivative, a benzene derivative, a phenyl derivative, a chloromethylketone or derivative thereof, a fluoromethylketone or derivative thereof, an alphaketo acid or derivative thereof, a ketoamide or derivative thereof, a ketoester or derivative thereof, a vinylsulfone or derivative thereof, and a pyridyl or derivative thereof.

15. (AMENDED) The pharmaceutical composition of claim 12 wherein R comprises a fluoromethylketone (FMK).

17. (AMENDED) The pharmaceutical composition of claim 11 wherein the inhibitor molecule inhibits cyst wall cysteine proteinase derived from *T. solium* or *T. crassiceps*.

A<sup>4</sup>  
18. (AMENDED) A pharmaceutical composition comprising Z-Leu-Leu-Leu-FMK or Z-Leu-Leu-Tyr-FMK; and a pharmaceutically acceptable carrier.

19. (AMENDED) A method for treating human neurocysticercosis comprising administering to a human subject the pharmaceutical composition of claim 18.

20. (AMENDED) A method for treating porcine cysticercosis comprising administering to a porcine subject the pharmaceutical composition of claim 18.

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21. (AMENDED) A method for treating human neurocysticercosis or porcine cysticercosis comprising administering to a human or porcine subject a pharmaceutical composition comprising an inhibitor molecule that inhibits the activity of a *Taenia* cysteine protease, the inhibitor molecule comprising a peptide or peptidomimetic compound; and a pharmaceutically acceptable carrier.

22. (AMENDED) The method of claim 21 wherein the peptide or peptidomimetic compound comprises (Xaa)<sub>n</sub>-Yaa-Zaa-R; wherein Xaa and Zaa are each independently any amino acid; Yaa is a hydrophobic amino acid; R comprises a nucleophilic moiety; and n = 0-5.

23. (AMENDED) The method of claim 22 wherein Yaa is leucine.

24. (AMENDED) The method of claim 22 wherein R comprises a chemical moiety selected from the group consisting of a carboxylic acid derivative, an amide derivative, a benzene derivative, a phenyl derivative, a chloromethylketone or derivative thereof, a fluoromethylketone or derivative thereof, an alphaketo acid or derivative thereof, a ketoamide or derivative thereof, a ketoester or derivative thereof, a vinylsulfone or derivative thereof, and a pyridyl or derivative thereof.

25. (AMENDED) The method of claim 22 wherein R comprises a fluoromethylketone (FMK).

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28. (AMENDED) The method of claim 26 wherein R comprises a chemical moiety selected from the group consisting of a carboxylic acid derivative, an amide derivative, a benzene derivative, a phenyl derivative, a chloromethylketone or derivative thereof, a fluoromethylketone or derivative thereof, an alphaketo acid or derivative thereof, a ketoamide or derivative thereof, a ketoester or derivative thereof, a vinylsulfone or derivative thereof, and a pyridyl or derivative thereof.

29. (AMENDED) The method of claim 26 wherein R comprises a fluoromethylketone (FMK).

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31. (AMENDED) The method of claim 26 performed in cell free environment.

A<sup>6</sup>  
32. (AMENDED) The method of claim 26 performed in cell culture, in an organ, or in a tissue.

33. (AMENDED) The method of claim 26 performed in a whole animal.

34. (AMENDED) The method of claim 26 wherein the *Taenia* cysteine proteinase is derived from *T. solium*.

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A<sup>7</sup>  
39. (AMENDED) The method of claim 37 wherein the inhibitor is Z-Leu-Leu-Leu-FMK or Z-Leu-Leu-Tyr-FMK.

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A<sup>8</sup>  
42. (AMENDED) The method of claim 40 wherein inhibitor is Z-Leu-Leu-Leu-FMK or Z-Leu-Leu-Tyr-FMK.

43. (AMENDED) The method of claim 40 wherein the animal is a pig or a human and the *Taenia* infection is a *T. solium* infection.

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44. (NEW) The method of claim 9 wherein the animal is a pig or a human and the *Taenia* infection is a *T. solium* infection.

A<sup>9</sup>  
45. (NEW) The method of claim 38 wherein the inhibitor is Z-Leu-Leu-Leu-FMK or Z-Leu-Leu-Tyr-FMK.

46. (NEW) The method of claim 41 wherein inhibitor is Z-Leu-Leu-Leu-FMK or Z-Leu-Leu-Tyr-FMK.

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47. (NEW) The method of claim 41 wherein the animal is a pig or a human and the *Taenia* infection is a *T. solium* infection.

48. (NEW) The method of claim 42 wherein the animal is a pig or a human and the *Taenia* infection is a *T. solium* infection.

| Year | 1960 | 1961 | 1962 | 1963 | 1964 | 1965 | 1966 | 1967 | 1968 | 1969 | 1970 | 1971 | 1972 | 1973 | 1974 | 1975 | 1976 | 1977 | 1978 | 1979 | 1980 | 1981 | 1982 | 1983 | 1984 | 1985 | 1986 | 1987 | 1988 | 1989 | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 | 2030 | 2031 | 2032 | 2033 | 2034 | 2035 | 2036 | 2037 | 2038 | 2039 | 2040 | 2041 | 2042 | 2043 | 2044 | 2045 | 2046 | 2047 | 2048 | 2049 | 2050 | 2051 | 2052 | 2053 | 2054 | 2055 | 2056 | 2057 | 2058 | 2059 | 2060 | 2061 | 2062 | 2063 | 2064 | 2065 | 2066 | 2067 | 2068 | 2069 | 2070 | 2071 | 2072 | 2073 | 2074 | 2075 | 2076 | 2077 | 2078 | 2079 | 2080 | 2081 | 2082 | 2083 | 2084 | 2085 | 2086 | 2087 | 2088 | 2089 | 2090 | 2091 | 2092 | 2093 | 2094 | 2095 | 2096 | 2097 | 2098 | 2099 | 2100 |
|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| 1960 | 1961 | 1962 | 1963 | 1964 | 1965 | 1966 | 1967 | 1968 | 1969 | 1970 | 1971 | 1972 | 1973 | 1974 | 1975 | 1976 | 1977 | 1978 | 1979 | 1980 | 1981 | 1982 | 1983 | 1984 | 1985 | 1986 | 1987 | 1988 | 1989 | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 | 2030 | 2031 | 2032 | 2033 | 2034 | 2035 | 2036 | 2037 | 2038 | 2039 | 2040 | 2041 | 2042 | 2043 | 2044 | 2045 | 2046 | 2047 | 2048 | 2049 | 2050 | 2051 | 2052 | 2053 | 2054 | 2055 | 2056 | 2057 | 2058 | 2059 | 2060 | 2061 | 2062 | 2063 | 2064 | 2065 | 2066 | 2067 | 2068 | 2069 | 2070 | 2071 | 2072 | 2073 | 2074 | 2075 | 2076 | 2077 | 2078 | 2079 | 2080 | 2081 | 2082 | 2083 | 2084 | 2085 | 2086 | 2087 | 2088 | 2089 | 2090 | 2091 | 2092 | 2093 | 2094 | 2095 | 2096 | 2097 | 2098 | 2099 | 2100 |      |